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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, KBI INC., and KBI-E INC., Plaintiffs and Counterclaim Defendants, v. HANMI USA, INC., HANMI PHARMACEUTICAL CO., LTD., HANMI FINE CHEMICAL CO., LTD, and HANMI HOLDINGS CO., LTD., Defendants and Counterclaim Plaintiffs.	**(FILED UNDER SEAL)** Civil Action No. 3:11-CV-00760-JAP-TJB **MEMORANDUM OF POINTS AND AUTHORITIES IN OPPOSITION TO PLAINTIFFS' MOTION FOR INJUNCTION PENDING APPEAL**

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I. PRELIMINARY STATEMENT AND RESERVATIONS

Following AstraZeneca's August 20, 2013 Motion for Injunction Pending Appeal, and receipt of the parties' respective letters to the Court on Monday, August 26th concerning the injunction briefing schedule and Hanmi's request for an opportunity for discrete discovery, the Court held a conference with counsel on August 27th. During that conference the Court: (1) stated its expectation that the pending motion could be resolved quickly; (2) indicated that Hanmi's requested discovery at this point appeared to be unnecessary to oppose Plaintiffs' motion; and (3) ordered that Hanmi submit on September 6, 2013, a focused response directed to the issue of "likelihood of success on the merits" on claim construction, and addressing "lack of irreparable harm" principally relying on the parties' Settlement Agreement, filed under seal by Hanmi on August 26th, without taking the requested discovery at this time. The Court further advised that if upon review of the motion and Hanmi's limited opposition, AstraZeneca is found to have actually made the requisite showing of likelihood of success on the merits, and surpassed a minimum threshold showing of irreparable harm despite the Settlement Agreement, Hanmi will be permitted to pursue discovery (as referenced and described in its August 26th letter to the Court) and then supplement its opposition to present a full factual record and corresponding response to AstraZeneca's positions on irreparable harm, balance of hardships and public interest.

Accordingly, Hanmi herein addresses the ***un***likelihood of success on the merits, presents a limited response to Plaintiffs' claim of irreparable harm in accordance with the Court's directions, and includes brief comments on balance of hardships and public interest. Hanmi expressly reserves the right to pursue the discovery it served on August 23rd, and to supplement

its opposition on the irreparable harm, balance of hardships and public interest factors should the Court determine that it is not prepared to deny Plaintiffs' motion on the present record.[1]

The Court stated on the August 27th call with counsel that it would not be granting the temporary restraining order that AstraZeneca had requested, seeking to block the launch pending resolution of the PI motion. For the reasons stated herein, AstraZeneca has not and cannot meet the requirements for obtaining injunctive relief, whether in the form of a temporary restraining order (as already determined by the Court[2]) or a preliminary injunction pending appeal.

II. BRIEF SUMMARY OF ARGUMENT

In the Consent Judgment entered June 3, 2013 (D.I. 338), AstraZeneca conceded that Hanmi does not infringe the two patents-in-suit under the Court's controlling claim constructions. Hanmi won the case. In terms of likelihood of success on appeal, AstraZeneca's brief merely rehashes its prior claim construction arguments and should not cause the Court to seriously rethink its sound constructions, made on a full record, and affirmed on reconsideration. No new facts or change in law are presented by AstraZeneca to even remotely suggest a basis for success on the merits. *See* Section III-A-1, *infra.* Further, AstraZeneca places great reliance on its assumption that "literal infringement" will result if the Federal Circuit modifies the claim construction, but that position misstates the pretrial record as shown below. In fact, even in the unlikely event of a modified construction, AstraZeneca still cannot prove infringement down the road. Likelihood of success is negated for this additional reason. *See* Section III-A-2, *infra.*

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[1] Following the call with the Court on August 27th, Hanmi tabled the noticed depositions, and agreed that the outstanding disputes over the scope of requested documents would also be deferred. (*See* Ex. A, Boland to Renk, August 27th.) Hanmi has not received any objections to its Rule 30(b)(6) deposition topics.

[2] Although not yet formalized in an Order, in view of the Court's call with counsel on August 27th, denying the TRO request, the TRO issue is moot and not separately addressed in this brief.

Likewise, AstraZeneca has not satisfied -- and cannot satisfy -- its burden of proving irreparable harm. [redacted] Despite all its untested and distorted market-based arguments alleging irreparable harm, AstraZeneca elected not to reference this most fundamental piece of evidence in its 31-page brief and lengthy declarations. The extraordinary remedy of injunctive relief is not available when the alleged harm can be compensated by an award money damages. *See, e.g., Eli Lilly & Co. v. American Cyanamid Co.*, 82 F.3d 1568, 1578-79 (Fed. Cir. 1996). Where, as here, a settlement agreement concludes a case with a concession of no infringement [redacted] irreparable harm simply cannot be shown because the parties have agreed that the future market damage, if any, is readily calculable. Indeed, [redacted] AstraZeneca cannot prove irreparable harm under these circumstances. *See* Section III-B, *infra.*

To Hanmi's knowledge no court has ever granted a patentee's preliminary injunction request pending appeal, where the patentee conceded no infringement and a corresponding settlement agreement provided [redacted] To grant an injunction here would be unprecedented, at odds with decades of black letter law on the stringent standards for injunctive relief, and inconsistent with the core legislative framework of the Hatch-Waxman Act. Hanmi respectfully requests that the pending motion be denied.

III. ARGUMENT

A preliminary injunction is an extraordinary remedy that is not to be "routinely granted."

Nat'l Steel Car, Ltd. v. Canadian Pac. Ry., Ltd, 357 F. 3d 1319, 1324 (Fed. Cir. 2004). A party seeking such drastic relief must establish four elements: (1) likelihood of success on the merits; (2) likelihood of irreparable harm in the absence of preliminary relief; (3) that the balance of equities tips in favor or granting preliminary relief; and (4) that an injunction is in the public interest. *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008); *PHG Techs., LLC v. St. John Cos*., Inc., 469 F.3d 1361, 1365 (Fed. Cir. 2006). The burden of making a "clear showing" of entitlement to such relief always lies with the movant. *Winter*, 555 U.S. at 22. If a party fails to meet its burden on any one of the four factors, a trial court will deny a motion for preliminary relief. *See Reebok Int'l Inc. v. J Baker, Inc*., 32 F.3d 1552, 1555-56 (Fed. Cir. 1994).

A. AstraZeneca Is Not Likely To Succeed On The Merits

To obtain an injunction, pending appeal, a movant must typically establish a ***strong likelihood*** of success on the merits. *Hilton v. Braunskill,* 481 U.S. 770, 778 (1987); *see also Pfizer, Inc., v. Teva Pharms., USA Inc.,* 429 F.3d 1364, 1381 (Fed. Cir. 2005) (movant must make a ***strong showing*** of likelihood of success). Here, AstraZeneca's showing is based on its twice-denied construction of "alkaline-salt," with no new facts or change in law. Making a third run at claim construction cannot fairly be considered a "strong showing" of likelihood of success, particularly where no new arguments are raised.

1. The Court's Claim Construction Is Correct And Is Highly Unlikely To Be Modified on Appeal

a) The Court's Construction Is Firmly Supported By The Record And AstraZeneca Has No New Facts Or Law

Based on the clear weight of intrinsic evidence and a straightforward application of claim construction principles, the Court has twice confirmed that the meaning of "alkaline salt" is directed to the six species disclosed in the '504 patent specification, specifically "Na^+, Mg^{2+}, Li^+, K^+, Ca^{2+} or $N^+(R)_4$ salt." (D.I. 257 at 3-8, 11-13.) As determined by this Court, "the patentee

has given a definition to 'alkaline salts' that governs construction of this term." (D.I. 257 at 6.) The Court expressly found that "[t]he '504 patent is clear and consistently states that the compounds of the invention are the identified five inorganic salts (Na^+, Mg^{2+}, Li^+, K^+, Ca^{2+}) and the one organic genus of salts ($N^+(R)_4$) of an enantiomer of omeprazole." (*Id.*; *see* '504 patent, Abstract; col 2, lines 42-49 ("***[t]he present invention refers to the new Na^+, Mg^{2+}, Li^+, K^+, Ca^{2+} or $N^+(R)_4$ salts*** of the single enantiomers of omeprazole…" (emphasis added).) The Court's determination of an express salt definition is well supported by Federal Circuit precedent, where patentees have used the same or similar language to define the scope of the invention. *See, e.g., Martek Biosciences Corp. v. Nutrinova, Inc.*, 579 F.3d 1363, 1380 (Fed. Cir. 2009) ("When a patentee explicitly defines a claim term in the patent specification, the patentee's definition controls."); *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1051-1052 (Fed. Cir. 2010) ("The specification need not reveal such a definition explicitly…."); *Bell Atl. Network Servs., Inc. v. Covad Commc'ns Group, Inc.*, 262 F.3d 1258, 1268 (Fed. Cir. 2001). Where use of a claim term throughout the patent documents is consistent with only a single meaning, that term has been defined by implication. *See Bell Atl. Network Servs.*, 262 F.3d at 1271; *see also Vitronics Corp. v. Conceptronic, Inc*., 90 F.3d 1576, 1582 (Fed. Cir. 1996); *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313, 1316 (Fed. Cir. 2005) (*en banc*) ("[T]he specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor's lexicography governs."). "[W]here, as here, the specification reveals a special meaning for a term that differs from the meaning it might otherwise possess, that special meaning governs, particularly when it also serves to avoid an inoperable claim construction." *AIA Eng'g Ltd. v. Magotteaux Int'l S/A,* 657 F.3d 1264, 1278 (Fed. Cir. 2011).

Perhaps more telling, the Federal Circuit has repeatedly found statements expressly characterizing *the invention* of a patent to limit the scope of that invention (such as statements

used by patentee here). *See, e.g., Honeywell Int'l, Inc. v. ITT Indus.*, 452 F.3d 1312, 1318 (Fed. Cir. 2006) (even though the claim used broader language, invention was limited to a fuel filter because the specification referred to the fuel filter as "this invention" and "the present invention"); *C.R. Bard, Inc. v. United States Surgical Corp*., 388 F.3d 858, 864-66 (Fed. Cir. 2004); *Trading Techs. Int'l, Inc. v. eSpeed, Inc.,* 595 F.3d 1340, 1353 (Fed. Cir. 2010); *Verizon Servs. Corp. v. Vonage Holdings Corp.*, 503 F.3d 1295, 1308 (Fed. Cir. 2007); *Cultor Corp. v. A.E. Staley Mfg. Co.*, 224 F.3d 1328, 1331 (Fed. Cir. 2000). A patentee may not rely on phrases pulled out of context from the specification and improperly applied to the claims in order to distort a construction. *Bristol-Myers Squibb Co. v. Apotex, Inc.*, 2013 U.S. Dist. LEXIS 44481, *23 (D.N.J. Mar. 28, 2013).

Having already considered AstraZeneca's arguments for a broad construction based on out-of-context specification quotes and misplaced arguments, the terms "alkaline salt" ('504 patent) and "pharmaceutically acceptable salt" ('192 patent) have been correctly construed by the Court to mean "Na^+, Mg^{2+}, Li^+, K^+, Ca^{2+} or $N^+(R)_4$ salt." (*See* D.I. 257 at 3-8, 11-13.) The Court's construction is on strong footing factually and legally. Contrary to the AstraZeneca's assertions, the intrinsic evidence consistently and unequivocally supports the Court's construction.

'504 Specification -- The specification unambiguously establishes that the "present invention" is limited to the six named salt species. ('504 patent, Abstract, cover page; col. 2, lines 42-49.) AstraZeneca merely rehashes its twice rejected arguments, while packaging them in a manner which distorts and purports to rewrite the specification to suit its needs. Despite the Abstract on the cover page of the patent and col. 2, lines 42-49 clearly delineating the scope of the alleged invention as the six salt species, on which the Court properly relied, AstraZeneca argues that other

passages in the '504 patent signal a broader concept of "alkaline salts." However, when each such passage *is properly read in context*, AstraZeneca's points clearly lack merit.

First, AstraZeneca asserts that col. 1, lines 8-9 support a broad construction of "salts." Mem., p. 15. However, that passage appears in the "Field of the Invention" section, which merely describes the technical area or *field* of the patent, and by definition does not purport to limit the patent's scope.

Second, AstraZeneca asserts that col. 1, lines 53-55 support a broad construction of "novel salts." Mem., p. 15. However, AstraZeneca argues the quotation from the paragraph at col. 1, lines 50-55 --

> It is desirable to obtain compounds with improved pharmacokinetic and metabolic properties which will give an improved therapeutic profile such as a lower degree of interindividual variation. The present invention provides such compounds, which are novel salts of single enantiomers of omeprazole.

-- entirely out of context. The paragraph is written to identify a need in the first sentence, and then states that "[t]he present invention" meets that need. Of course, "the present invention" is defined in unambiguous terms at col. 2, lines 42-49, and one of ordinary skill in the art would not interpret the 1:50-55 general statement of need/solution to mean that the "novel salts of single enantiomers of omeprazole" would encompass any salts beyond the six plainly defined as *the invention*. AstraZeneca's reliance on col. 2, lines 53-55 ignores the entire context of the '504 patent, including the fact that the reader has already been directed to the Abstract on the cover page, indicating clearly that the alleged invention of "novel salts" is the six salt species:

> The novel optically pure compounds Na^+, Mg^{2+}, Li^+, K^+, Ca^{2+} and $N^+(R)_4$ salts of [the enantiomers of omeprazole] … processes for the preparation thereof and pharmaceutical preparations containing the compounds as active ingredients, as well as the use of the compounds in pharmaceutical preparations and intermediates obtained by preparing the compounds.

('504 patent, Abstract.)

Third, AstraZeneca asserts that col. 1, lines 56-58 support a broad construction of "salts." Mem., p. 15. However, that passage is directed to a *preferred embodiment*, where the emphasis in

context is clearly on the "pure crystalline" aspects of the six salts previously announced in the Abstract, and subsequently defined with specific boundaries at col. 2, lines 42-49. In accordance with this preferred embodiment, dependent claim 4 of the '504 patent specifies that the salt compound is "substantially crystalline," and all claims were amended in prosecution to specify that the salts are "pure."

Fourth, AstraZeneca asserts that col. 5, *line 7* supports a broad construction of "salts." Mem., p. 15. However, that one line is part of a paragraph that, when properly read in context, clearly cannot broaden the crystal clear definition of the six salts presented in the Abstract and repeated at col. 2, lines 42-49. Indeed, this precise portion of the specification was briefed extensively on the *Markman* record and not found to be a broadening of the express definitional scope presented earlier in the specification. AstraZeneca's argument (Mem., p. 15) that the alkaline salts of the invention are "merely 'exemplified by' the six enumerated salts" is an improper rewrite of the specification language, and a cropped quote. The full text is as follows:

> Alkaline salts of the single enantiomers of the invention are, as mentioned above, beside the sodium salts (compounds Ia and Ib) and the magnesium salts (compunds IIa and IIb), exemplified by their salts with Li^+, K^+, Ca^{2+} and $N^+(R)_4$, where R is an alkyl with 1-4 C-atoms.

('504 patent, col. 5, lines 7-11.) In context, this passage refers to "[a]lkaline salts of the single enantiomers ***of the invention***…" and lists the same six salts ***of the invention*** that were previously defined in the Abstract and at col. 2, lines 42-49, as the six salt species.

Fifth, AstraZeneca ignores all of the working Examples in the '504 patent, which only describe preparations of Na^+ and Mg^{2+} salts – not even the full complement of six. Thus, the working Examples of two salt forms purport to exemplify the genus of six salts. The '504 patent nowhere states that the six salts are merely exemplary of a broader class of unnamed and undisclosed "alkaline salts".

As the entire specification and supporting record makes clear, the '504 patent consistently and unambiguously sets forth the scope of the alleged invention as six novel salts, and nothing more. AstraZeneca's cited authorities, based on the specification not clearly limiting scope, are inapposite.

Prosecution History -- AstraZeneca argues that the patent examiner "intended" the term ***alkaline salt*** to have a scope broader than the six particular exemplary salts listed in the specification. Mem. pp. 9, 16. This is speculative attorney argument, without support in the record. It is axiomatic under 35 U.S.C. § 112, first paragraph, that claims cannot be broader than the supporting disclosure in the specification, and any argument that the examiner "intended" to allow a claim broader than the disclosure ignores § 112 and cannot be correct.

The examiner interview summary record stated that "A pharmaceutical formulation for oral administration of pure solid state (-) enantiomer of omeprazole Na-salt may be allowable *after reviewing the data in affidavit form*. . . . *The scope of the claim will depend on the data submitted.*" (D.I. 111, Interview Summary at HAN0039582 (emphasis added).) The only thing the examiner's statement makes clear was that she would consider allowing a claim to a single species, defined as a (1) pure (2) solid-state (3) (-)-enantiomer of omeprazole (4) Na^+-salt, ***if*** the declaration evidence demonstrated patentability over the asserted prior art.

In response, AstraZeneca submitted the Declaration of Dr. Andersson reporting on two clinical studies involving only the sodium salt and the magnesium salt of (-)-omeprazole. Based on the clinical data reported, AstraZeneca argued for patentability, in that the results were specifically attributed to the sodium and magnesium salts used in the clinical studies. (D.I. 111-2, Andersson Declaration at HAN0039773-94.) When AstraZeneca submitted the Anderson Declaration, it canceled all existing claims and submitted new claims -- the broadest of which

substituted "alkaline salt" for the six recited species of the originally filed claims.[3] Citing no support within the specification for its broadening amendment, and based on a Declaration describing the testing of only two salts species of (-)-omeprazole, AstraZeneca asserted that the data on the two salt species "***support[ed] the full scope of the genus of alkaline salts disclosed in the application and as claimed herein.***" (D.I. 111-2, February 12, 1997 Amendment at pp. 4-5.)

AstraZeneca now argues that "the patent examiner agreed and allowed the new, broader claims as submitted" (Mem. p. 6). While the allowed claims covered six salt species in pure solid state form, and provide for greater protection than the previously unallowed claims, or even a claim to a single Na salt species, in no event can the full scope of "alkaline salt" encompass more than the six disclosed species. After all, applicants stated directly that the full scope of the genus disclosed in the application was limited to the six species actually recited. (*See* D.I. 111-2, February 12, 1997 Amendment at pp. 4-5 (emphasis supplied).) There was not then, and is not now, any evidence of record showing that the scope of alkaline salts is any broader than the actual disclosure of the six recited species.

AstraZeneca's acquiescence in the Examiner's statement that "[t]*he scope of the claim will depend on the data submitted,*" requires a claim scope that is limited to the named species (based on "*the data submitted*" by the applicants), and is consistent with a straightforward reading of the specification. *TorPharm Inc. v. Ranbaxy Pharms., Inc*., 336 F.3d 1322, 1330 (Fed. Cir. 2003) ("[A]scertaining the scope of an issued patent, the public is entitled to equate an inventor's acquiescence to the examiner's narrow view of patentable subject matter with

[3] The fact that all of the original claims of the '512 application were limited to the six salts (Mem. p. 5) is strong evidence that the inventors were never in possession of a broader, undisclosed genus. (*See* D.I. 111 at HAN0039543-49.)

abandonment of the rest. Such acquiescence may be found where the patentee narrows his or her claims by amendment, or lets stand an examiner's restrictive interpretation of a claim.") (internal citations omitted).

AstraZeneca's mistaken arguments about claim breadth are based on the erroneous predicate that the six species described in the specification are "exemplary" of a broader genus. Mem. p. 16. The patent specification refutes this predicate, however, by never suggesting that the six salts described as "the present invention" are exemplary of a much larger undisclosed genus. Rather, the patent specification and prosecution history refer at best to the preparation of two species – Mg and Na – as representative of the broader genus of six salts. That is the scope disclosed in the specification, and that is the scope the examiner intended to confer upon allowing a claim to an "alkaline salt."

Having twice considered and rejected AstraZeneca's flawed arguments about the prosecution history based on a clear application of controlling Federal Circuit precedent, there is little if any chance the Federal Circuit would modify this Court's construction based on vague speculations as to the prosecution history, and so AstraZeneca's showing of likelihood of success – as well as its motion – must fail.

Claim Differentiation -- In its *Markman* submissions and its later-denied motion for reconsideration, AstraZeneca argued and reargued claim differentiation in support of its broad construction. The Court has twice determined that the intrinsic evidence trumps and overcomes the rebuttable presumption of claim differentiation. Again, no new facts or change in law are presented, and the Court's determination that the presumption has been overcome – especially by the clear and unmistakable definition of salt scope in the '504 specification, which *inter alia* provides the necessary evidence to overcome the presumption – has not been shown to be erroneous. The Federal Circuit has made clear that "different terms or phrases in separate claims may be construed to

cover the same subject matter where the written description and prosecution history indicate that such a reading . . . is proper." *Hologic, Inc. v. Senorx, Inc.,* 639 F.3d 1329, 1337 (Fed. Cir. 2011) (citing *Nystrom v. TREX Co.*, 424 F.3d 1136, 1143 (Fed. Cir. 2005)); *Curtiss-Wright Flow Control Corp. v. Velan, Inc*., 438 F.3d 1374, 1380-81 (Fed. Cir. 2006) ("Indeed this court has acknowledged that two claims with different terminology can define the exact same subject matter."). That is precisely the case here.

Not one of the cases relied upon by AstraZeneca justify a different result than the one this Court has twice reached. In *SunRace Roots Enter. Co., Ltd. v. SRAM Corp.*, 336 F.3d 1298 (Fed. Cir. 2003), both parties *acknowledged* that the specification contained *no* explicit definition of the term "shift actuator." *Id.* at 1302. That is exactly the opposite of the present case. In *SanDisk Corp. v. Kingston Technology Co.*, 695 F.3d 1348 (Fed. Cir. 2012), the Federal Circuit reversed a narrow construction of "recording a relative time of programming…" as improperly limited to a single method for identifying the physical page containing the most recent version of data with the same logical address, where the specification clearly disclosed two such methods. *Id.* at 1356-57. *Sandisk* is irrelevant here, where the Court has already construed "alkaline salt" to mean all of the salts disclosed in the specifications, *i.e., none were excluded*. In *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898 (Fed. Cir. 2004), no evidence was offered to rebut the presumption of claim differentiation. ("Although that presumption can be overcome if the circumstances suggest a different explanation, or if the evidence favoring a different claim construction is strong, the presumption is unrebutted in this case, *as Medrad has offered no alternative explanation for why the "pressure jacket" limitation is found in the dependent claims but not in the corresponding independent claims*."). *Id*. at 910 (emphasis added). Factually, *Liebel-Flarsheim* has nothing to do with this case because Hanmi has explained repeatedly how the express definition and other factors overcome the general presumption. Finally, in

Interdigital Communications v. ITC, 690 F.3d 1318 (Fed. Circ. 2012), the Federal Circuit stated that the presumption of claim differentiation could be overcome by "strong contrary evidence such as *definitional language in the patent* or a clear disavowal of claim scope, [but that] neither type of contrary evidence is present here." *Id.* at 1324-25 (emphasis added). Because of *at least* the express definition provided in the '504 patent, *Interdigital* is inapplicable here.

b) The Court Properly Denied AstraZeneca's Motion For Reconsideration on Claim Construction

AstraZeneca sought reconsideration of the Court's construction of the terms "alkaline salt" and "pharmaceutically acceptable salt," but the Court declined to alter its construction (D.I. 283). The present arguments on likelihood of success amount to a ***third*** bite at the apple which, not surprisingly, have been routinely met with judicial skepticism. *Cf., Prall v. Bocchini*, Civ. A. 10-1228 JBS, 2012 WL 5465161, at *2 (D.N.J. Nov. 7, 2012) (denying plaintiff's second motion for reconsideration and finding that "[plaintiff's] only recourse, if he disagrees with this Court's decision, should be via the normal appellate process. He may not use this second motion for reconsideration to re-litigate a matter that has been thoroughly adjudicated by the Court.").

c) Statistics Favor Affirmance of The Court's Construction

Moreover, statistics do not support AstraZeneca's argument that the Federal Circuit will "likely" reverse this Court's construction of "alkaline salt." To the contrary, statistics confirm that the Federal Circuit will likely ***affirm*** this Court's construction. Recent empirical studies of claim construction reversal rates demonstrate that the Federal Circuit has – in the past several years – affirmed District Court claim constructions more than 75% of the time. Statistically, AstraZeneca cannot prove a modification of the construction is likely on appeal.

In a 2012 review of 1,034 claim construction rulings between January 1, 2000 and December 31, 2011, Anderson and Mennel report that – since the *Phillips* decision in 2005 – the

Federal Circuit has reversed a claim construction decision 25.1% of the time, resulting in a remand, reversal and/or vacation in only 22.1% of the cases. *See* J. Jonas Anderson & Peter S. Menell, *Informal Deference: An Historical, Empirical, And Normative Analysis of patent Claim Construction*, NW. U. L. REV. (forthcoming) (manuscript at 38), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2150360 (Ex. C). An affirmance rate of about 75%-78% certainly does not suggest a likely reversal here, particularly given the strength of the record supporting the Court's construction.

In a 2013 review of 260 claim construction rulings from January 1, 2010 – March 30, 2013, Cotropia reports an overall reversal rate of 26.5% of at least one term of a District Court's claim construction ruling, and a reversal rate of less than 25% for the first quarter of 2013 alone. *See* Ex. D, Christopher Anthony Cotropia, *Is Patent Claim Interpretation Review Deference or Correction Driven?,* Working Paper May 16, 2013 at 7-8, *available at* http://ssrn.com/abstract=2265962 or http://dx.doi.org/10.2139/ssrn.2265962.

Again, a statistical affirmance rate of 75% or more squarely refutes AstraZeneca's unsupported arguments regarding a ***likely*** reversal. Further weighing against AstraZeneca's arguments is Cotropia's finding that for claim construction appeals based on patentee losses at the District Court, the Federal Circuit changed the District Court's claim construction (resulting in a reversal or vacate and remand of the case) only 23% of the time. *See id.* at 14. While these studies are not dispositive, they provide statistical evidence of the Federal Circuit's results in deciding claim construction appeals, and demonstrate that any ***likely*** reversal is, in fact, ***unlikely***.[4]

[4] AstraZeneca makes much of *de novo* claim construction review. But as the Cotropia and Anderson references make clear, the declining reversal rates for the Federal Circuit over the past several years are not based on lack of deference to District Court decisions. That view is confirmed in Thomas W. Krause & Heather F. Auyang, *What Close Cases and Reversals Reveal*

2. AstraZeneca's Assumption That Literal Infringement Will Result Upon Modification Of Claim Construction Is Incorrect And Misstates The Pretrial Record

Absent a modification of this Court's construction of the term "alkaline salt," there can be no possibility of infringement of the '504 and '192 patents. AstraZeneca has expressly conceded that under the Court's claim construction, Hanmi's esomeprazole strontium product does not infringe the '504 and '192 patents (*see* Ex. B, Settlement Agreement, § 3.8), and agreed not to argue infringement under the doctrine of equivalents in any litigation or proceeding, including the Federal Circuit Appeal (§ 3.7).

Nonetheless, throughout its brief, AstraZeneca argues that if its claim construction is adopted by the Federal Circuit, Hanmi's esomeprazole strontium tetrahydrate product would "literally infringe" claim 1 of the '504 patent. *See, e.g.*, Mem., pp. 2-3, 9-10, 13 and 18-20. However, AstraZeneca's bold proclamations of literal infringement are dead wrong. Even if the salt construction is modified on appeal, AstraZeneca would find itself back in a contested infringement trial before this Court because Hanmi's Product would not infringe any asserted claim since its active ingredient is esomeprazole strontium *tetrahydrate*, and neither patent-in-suit encompasses hydrates. (*See* October 15, 2012 Order, granting Hanmi's motion to amend to assert non-infringement based on hydrates (D.I. 269); Pretrial Order (D.I. 326) at p. 5 (expected testimony of Wayne Genck), and Ex. E thereto, section 2.c (no infringement because Hanmi's product is a tetrahydrate); Second Expert Report of Wayne J. Genck (D.I. 290-11), and documents referenced therein.) Consistently, Article 4.3 of the Settlement Agreement also

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About Claim Construction at the Federal Circuit, 12 J. MARSHALL REV. INTELL. PROP. L. 583 (2013) (Ex. E). In any event, the Federal Circuit is currently revisiting the *de novo* review standard for claim construction *en banc* in *Lighting Ballast Control v. Phillips Electronics North America*, Appeal Nos. 2012-1014, 2012-1015, and has specifically raised the question of whether portions of a district court's *Markman* ruling should be entitled to deference. Oral argument before the *en banc* court is scheduled for September 13, 2013.

expressly contemplates a return to this Court to determine infringement in the event of Federal Circuit modification of claim construction because literal infringement ***does not*** follow directly from AstraZeneca's claim construction:

> 4.3. Provided that the Federal Circuit Appeal does not result in affirmance of the District Court's claim construction, nothing in this Agreement shall prevent or limit AstraZeneca's entitlement to seek a determination by the District Court that the Hanmi Product literally infringes the AstraZeneca Patents.

(Ex. B.)

Thus, AstraZeneca's repeated assertions of "literal infringement" and Hanmi's "infringing product" completely misrepresent the facts and the pretrial record. AstraZeneca's brief never mentions that Hanmi's defense of non-infringement based on hydrates remains to be resolved even if there is an unlikely reversal of the claim construction. These facts alone defeat any claim that AstraZeneca is likely to succeed on the merits. Moreover, Hanmi's likelihood of succeeding on the "hydrates" non-infringement defense are significantly bolstered by the Patent Office having granted Hanmi its own patent on its esomeprazole strontium tetrahydrate product, which issued directly over the AstraZeneca '504 and '192 patents. (*See, e.g.,* U.S. Patent 8,106,076 (D.I. 291, listing '504 and '192 patents on cover page; *see also* D.I. 290-11, Genck Report discussing '076 patent at paragraphs 108-114).)

B. AstraZeneca Cannot Establish Irreparable Harm

1. [redacted]

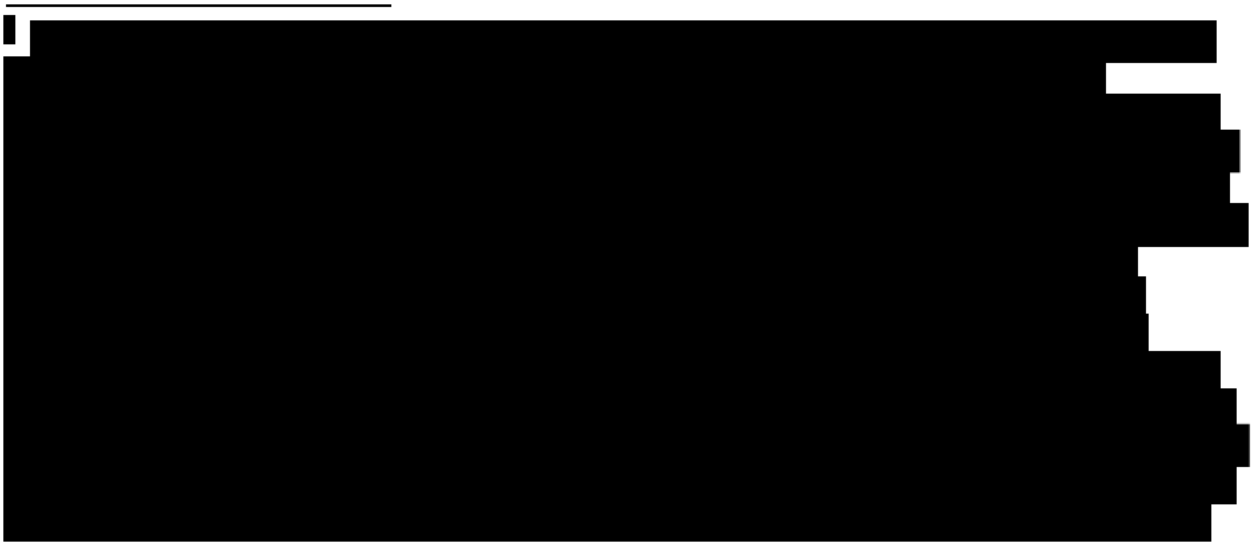
[redacted]

5 [redacted]

[redacted]

[redacted]

[redacted]



2. Even Absent The Settlement Agreement, Hanmi Can Establish There Is No Irreparable Harm Should The Court Desire A Full Record

In the event the Court desires a full factual record and briefing on irreparable harm, Hanmi can prove a number of important considerations stemming from the facts that Hanmi's Product is not a generic but a non AB-rated 505(b)(2) product,[10] and competition and market hurdles will significantly limit the impact of Hanmi's Product on the "Nexium® business," especially given the nature of Hanmi's Product. AstraZeneca's brief omits the public fact that the market will be genericized by Ranbaxy under license in May 2014, and that an over-the-counter (OTC) version of Nexium® is planned by agreement with Pfizer. Hanmi's Product thus has a narrow window for any possible impact on AstraZeneca's market. As AstraZeneca knows, the multiple hurdles faced by Hanmi's product (non-AB rating and no automatic substitution by physicians and pharmacists, a discrete temporal window prior to competition by a first generic entrant, an authorized OTC product, and later, other generic entrants) in penetrating a brand market with a 505(b)(2) non-AB rated product are fierce. *See* Nelson Decl'n, ¶¶ 7, 10-18, 28, 30. Thus, contrary to AstraZeneca's allegations, Hanmi's Product is likely to take a minor percentage of a very large market -- a market which discovery will prove is already being cannibalized by discounts, rebates, etc., and which has a short life-span in any event. *Id.*, ¶¶ 7, 12, 13, 18, 29. Indeed, similar products in the past have not destroyed the brand market, but instead took a minor share. *Id.*, ¶¶ 15-17.

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presumption of irreparable harm no longer is permissible in any event. *Robert Bosch LLC v. Pylon Mfg. Corp.*, 659 F.3d 1142, 1149 (Fed. Cir. 2011).

[10] In real world practice, a non AB-rated product means that a physician must specifically prescribe the product, unlike a generic which can be substituted for a brand product at will by the pharmacy or formulary. Nelson Decl'n, ¶¶ 11, 30.

Moreover, the patent holder seeking an injunction must establish a causal nexus between the alleged irreparable harm and the alleged infringement. *Apple, Inc. v. Samsung Electronics Co., Ltd.*, 695 F.3d 1370, 1374 (Fed. Cir. 2012). It is well-established that "neither the difficulty of calculating losses in market share, nor speculation that such losses might occur, amount to proof of special circumstances justifying the extraordinary relief of an injunction prior to trial." *Nutrition 21*, 930 F.2d at 871 (vacating preliminary injunction); *see also Novartis Corp. v. Teva Pharm. USA, Inc.*, 2007 U.S. Dist. LEXIS 42163, *90-91 (D.N.J. June 11, 2007) (possibility of lost sales, market share and price erosion "do not demand a preliminary injunction, especially where such losses, by all measure, appear to be calculable"). Here, AstraZeneca not only claims inability to measure alleged losses but goes so far as to present only a fractionated picture of the market, replete with omission of critical facts, and misplaced causal speculations by its declarants. Any Nexium® price erosion, and shifts in the market position of Nexium® may well result from AstraZeneca's own activities (*e.g.,* price slashing, extension of rebates, coupons and incentives, introduction of a licensed OTC version of Nexium® and/or other authorized products, and willingness to accept settlements with generic entrants selling copycat products at drastically reduced prices). These aspects are not fully briefed here in accordance with the Court's guidance, but are addressed without the benefit of discovery and extensive market analysis -- pending the Court's determination of any further lack of irreparable harm showing by Hanmi -- in the Declaration of Philip B. Nelson, Ph.D. [11]

[redacted]

C. The Balance Of Equities Weighs Against Enjoining Hanmi

The balance of hardships falls hard upon Hanmi. Indeed, it is Hanmi that in fact will suffer irreparable injury if AstraZeneca's motion is granted.[12] Hanmi's product development and ultimate launch strategy have relied on AstraZeneca's (1) representations to the public and the Patent Office in the asserted patent documents, (2) representations over the course of this litigation and (3) critically, upon AstraZeneca's concession of no infringement and money damages in the course of settling the underlying infringement action. AstraZeneca ignores the fact that Hanmi won the litigation by consent, and that the Settlement Agreement provides for contemplated reasonably royalty damages. The Hatch-Waxman statutory scheme has been fully complied with by Hanmi – a litigant who sought and obtained FDA approval, fought the patent litigation and won. In that scenario, the statutory scheme expressly permits product launch. [13]

[12] While the degree and extent of hardship to Hanmi is not fully briefed in the present paper, such bases have been summarily discussed in the Nelson Declaration at paragraphs 27-31. Hanmi reserves the right to supplement its balance of hardships showing if provided with an opportunity for discovery and complete briefing.

[13] AstraZeneca distorts the facts by calling the launch "at-risk" (*e.g.*, Mem. p. 1) and "premature" (*e.g.*, Mem. pp. 1-2). If Congress had envisioned that successful Hatch-Waxman litigants not be able to launch until after a district court victory *and appeal*, it would have said so and the entire Hatch-Waxman landscape over the past 25 years would be entirely different.

Relying on the patent landscape for Nexium®, the Hatch-Waxman statutory scheme and the express provisions of the parties' Settlement Agreement, Hanmi has borne significant expense and allocated major resources in designing its own unique product, procuring multiple U.S. patents related to that product, enduring the rigors of new drug application regulatory review per the 505(b)(2) pathway (versus the generic 505(j) pathway for abbreviated new drug applications), and in defending the patent litigation for over two-and-a-half years. Hanmi's investments target the launch opportunity within the narrow window presented to a 505(b)(2) entrant to introduce a competing product into the U.S. market, before true generic products -- fully substitutable for Nexium® -- would significantly affect Hanmi's ability to sell its non-AB rated product. (*See* Nelson Decl'n., ¶ 30.) The drastic remedy of injunctive relief now would result in irreparable injury to Hanmi.[14]

D. Issuance Of An Injunction Would Be Against Public Interest

The final factor in evaluating whether a preliminary injunction should issue is the impact of an injunction on the public interest.[15] *Illinois Tool Works, Inc. v. Grip-Pak, Inc.,* 906 F.2d 679, 681 (Fed. Cir. 1990). AstraZeneca's rote recitation of the public interest in protecting valid patent rights (Mem. pp. 30-31) does not satisfy AstraZeneca's burden. Especially when, as here, the patentee does not make a strong showing of likelihood of success on the merits, the interest in enforcing patent rights is offset by the legitimate right to compete. *See Illinois Tool Works,* 906 F.2d at 684. "The public has an interest in product availability," and the public interest does not favor protecting patent rights "from competition in the marketplace by products which do not

[14] Should the Court not deny the motion on the present record, Hanmi reserves the right to make a complete factual record following discovery on balance of the equities.

[15] The adverse economic impact on the public has not been fully briefed in the present paper, but has been summarily discussed in the Nelson Declaration at paragraph 32. Hanmi reserves the right to supplement its showing that an injunction would be against public interest if provided with an opportunity for discovery and complete briefing.

necessarily literally or equivalently infringe the patent." *Hewlett-Packard Co. v. GenRad, Inc.*, 882 F. Supp. 1141, 1154 (D. Mass. 1995). Here, the parties agreed (i) that Hanmi's esomeprazole strontium product does not infringe under the Court's claim construction and (ii) to reasonably royalty damages in the event of an ultimate finding of infringement after appeal. The public interest in protecting the exclusive rights afforded by the patent system, and thereby encouraging innovation and invention, is sufficiently protected by monetary damages. *See CollaGenex Pharms, Inc. v. IVAX Corp.*, 375 F. Supp. 2d 120, 140-141 (E.D.N.Y. 2005).

Moreover, the principal purpose of the Hatch-Waxman Act is "to increase competition in the drug industry" by facilitating the approval of non-branded drugs. *Id* at 141. Congress recognized the strong public interest in obtaining generic drugs at lower prices than branded drugs, and was clear in its expectation that increased competition would make available more low cost non-branded drugs. H.R. Rep. No 98-857, pt. 1, at 14 (1984), reprinted in 1984 U.S.C.C.A.N. 2647 (Ex. F). That interest is even further enhanced where, as here, new compounds are being developed and approved through the § 505(b)(2) pathway. With these considerations in mind, "the public's interest is not in the end best served by removing what may well be a non-infringing product from the market." *Pass & Seymour, Inc. v. Hubbell Inc.,* 532 F. Supp. 2d 418, 434 (N.D.N.Y. 2007) (internal quotations omitted); *see also Graceway Pharms., LLC v. Perrigo Co.,* 697 F. Supp. 2d 600, 609 (D.N.J. 2010) (public interest is enhanced by competition).

The public interest also is disserved by an injunction in this case because, upon an affirmance of this Court's claim construction, there will be no way for the Court to compensate

the public for having paid millions of dollars in monopoly prices to AstraZeneca in the interim. *See Boehringer Ingelheim Corp. v. Shalala,* 993 F. Supp. 1, 3 (D.D.C. 1997).[16]

IV. CONCLUSION

Hanmi respectfully submits that for at least the foregoing reasons, AstraZeneca's Motion for Injunction Pending Appeal should be denied.

Dated: September 6, 2013

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[16] In the event the Court is inclined to entertain further briefing on a full factual record, Hanmi will present its position on the appropriate amount of an injunction bond. *See* Nelson Declaration, ¶ 33.

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CERTIFICATE OF SERVICE

I, Mayra V. Tarantino, hereby certify that on September 6, 2013, I caused a copy of the foregoing **MEMORANDUM OF POINTS AND AUTHORITIES IN OPPOSITION TO PLAINTIFFS' MOTION FOR INJUNCTION PENDING APPEAL** to be served upon the following counsel by ECF and by electronic mail:

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